



## ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2022-0918; FRL-10490-01-OCSPP]

### Cumulative Risk Assessment; Science Advisory Committee on Chemicals (SACC); Request for Nominations of *ad hoc* Expert Reviewers and Notice of Public Meeting

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA or “Agency”) is seeking public nominations of scientific and technical experts that EPA can consider for service as *ad hoc* reviewers assisting the Science Advisory Committee on Chemicals (SACC) with the peer review of two draft documents entitled: “Draft Proposed Principles of Cumulative Risk Assessment Under the Toxic Substances Control Act” and “Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer Requested Phthalate Under the Toxic Substance Control Act.” The two draft documents will be submitted to the SACC and released for public review and comment in late February 2023. EPA is also announcing the scheduling of a 4-day virtual public meeting for the SACC to consider and review the two draft documents.

**DATES:** The following is a chronological listing of the dates for the specific activities that are described in more detail under **SUPPLEMENTARY INFORMATION**.

[INSERT DATE 30 DAYS FROM DATE OF PUBLICATION IN THE **FEDERAL REGISTER**] – Deadline for submitting all nominations to EPA.

April 24, 2023 – Deadline for submitting a request for special accommodations to allow EPA time to process the request before the meeting.

May 8 to 11, 2023, from 10:00 a.m. to approximately 5:30 p.m. (ET) – The public virtual meeting will be held via a webcast platform such as “Zoom.gov” and audio teleconference, and you must register to receive the links.

**ADDRESSES:** *Nominations:* Submit your nominations to the Designated Federal Official (DFO) listed under **FOR FURTHER INFORMATION CONTACT**.

*Special accommodations:* For information on meeting access or services for individuals with disabilities, and to request accommodation for a disability, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT**.

**FOR FURTHER INFORMATION CONTACT:** Contact the DFO, Dr. Alaa Kamel, Mission Support Division, Office of Program Support, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency; telephone number: (202) 564-5336 or call the SACC main office at (202) 564-8450; email address: *kamel.alaa@epa.gov*.

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. What action is the Agency taking?*

The Agency is seeking public nominations of scientific and technical experts that EPA can consider for service as *ad hoc* reviewers assisting the Science Advisory Committee on Chemicals (SACC) with the peer review of two draft documents entitled: “Draft Proposed Principles of Cumulative Risk Assessment Under the Toxic Substances Control Act” and “Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer Requested Phthalate Under the Toxic Substance Control Act.” EPA is also announcing the scheduling of a 4-day virtual public meeting for the SACC to consider and review the two draft documents. EPA will be soliciting comments from the SACC on the two draft documents on issues related to chemical grouping for purposes of CRA, health outcomes related to phthalate syndrome, and possible approaches to developing the cumulative hazard and exposure assessment for High-Priority phthalates and a Manufacturer-Requested phthalate.

This document provides instructions for submitting nominations for *ad hoc* reviewers, requesting special accommodations for the virtual public meeting, and accessing the materials provided to the SACC. EPA will publish a separate document in the *Federal Register* in late

February 2023 to announce the availability of and solicit public comment on the two draft documents, and instructions for submitting comments, and registering to provide oral comments.

*B. What is the Agency's authority for taking this action?*

The SACC was established by EPA in 2016 in accordance with the Toxic Substances Control Act (TSCA) section 26(o), 15 U.S.C. 2625(o), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Public Law 114-182, June 22, 2016, to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of TSCA. The SACC operates in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C. appendix 2 *et seq.*, and supports activities under the TSCA, 15 U.S.C. 2601 *et seq.*, the Pollution Prevention Act (PPA), 42 U.S.C. 13101 *et seq.*, and other applicable statutes.

*C. Does this action apply to me?*

This action is directed to the public in general. This action may, however, be of interest to those involved in the manufacture, processing, distribution, and disposal of chemical substances and mixtures, and/or those interested in the assessment of risks involving chemical substances and mixtures regulated under TSCA. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

*D. What should I consider as I submit my nominations to EPA?*

1. *Submitting CBI.* Do not submit CBI or other sensitive information to EPA through <https://www.regulations.gov> or email. If your nomination contains any information that you consider to be CBI or otherwise protected, please contact the DFO listed under **FOR FURTHER INFORMATION CONTACT** to obtain special instructions before submitting that information. For inclusion in the public docket, please submit a copy of the nomination that does not contain the information you consider to be CBI or otherwise protected.

2. *Tips for preparing comments.* When preparing and submitting your comments, see Tips for Effective Comments at <https://www.epa.gov/dockets>.

## II. Nominations for *ad hoc* Reviewers

### A. *What is the purpose of the SACC?*

The SACC provides independent scientific advice and recommendations to the EPA on the scientific and technical aspects of risk assessments, methodologies, and pollution prevention measures and approaches for chemicals regulated under TSCA. The SACC is comprised of experts in toxicology; environmental risk assessment; exposure assessment; and related sciences (e.g., synthetic biology, pharmacology, biotechnology, nanotechnology, biochemistry, biostatistics, physiologically based pharmacokinetic modelling (PBPK), computational toxicology, epidemiology, environmental fate, and environmental engineering and sustainability). The SACC currently consists of 17 members. When needed, the committee will be assisted by *ad hoc* reviewers with specific expertise in the topics under consideration.

### B. *Why is EPA seeking nominations for ad hoc reviewers?*

As part of a broader process for developing a pool of candidates for SACC peer reviews, EPA is asking the public and stakeholder communities for nominations of scientific and technical experts that EPA can consider as prospective candidates for service as *ad hoc* reviewers assisting the SACC with the peer reviews. Any interested person or organization may nominate qualified individuals for consideration as prospective candidates for this review by following the instructions provided in this document. Individuals may also self-nominate.

Those who are selected from the pool of prospective candidates will be invited to attend the public meeting and to participate in the discussion of key issues and assumptions at the meeting. In addition, they will be asked to review and to help finalize the meeting minutes.

### C. *What expertise is sought for this peer review?*

Individuals nominated for this SACC peer review, should have expertise in one or more of the following areas: Chemical mixtures risk assessment (especially with experience using dose additive component-based mixtures approaches, including relative potency factors); mode of action (MOA); phthalate toxicology; male reproductive toxicology; exposure assessment

(occupational, consumer, and general population exposure); biomonitoring data; and biostatistics. Nominees should be scientists who have sufficient professional qualifications, including training and experience, to be capable of providing expert comments on the scientific issues for this review.

*D. How do I make a nomination?*

By the deadline indicated under **DATES**, submit your nomination to the DFO listed under **FOR FURTHER INFORMATION CONTACT**. Each nomination should include the following information: Contact information for the person making the nomination; name, affiliation, and contact information for the nominee; and the disciplinary and specific areas of expertise of the nominee.

*E. Will ad hoc reviewers be subjected to an ethics review?*

SACC members and *ad hoc* reviewers are subject to the provisions of the Standards of Ethical Conduct for Employees of the Executive Branch at 5 CFR part 2635, conflict of interest statutes in title 18 of the United States Code and related regulations. In anticipation of this requirement, prospective candidates for service on the SACC will be asked to submit confidential financial information which shall fully disclose, among other financial interests, the candidate's employment, stocks and bonds, and where applicable, sources of research support. EPA will evaluate the candidates' financial disclosure forms to assess whether there are financial conflicts of interest, appearance of a loss of impartiality, or any prior involvement with the development of the documents under consideration (including previous scientific peer review) before the candidate is considered further for service on the SACC.

*F. How will EPA select the ad hoc reviewers?*

The selection of scientists to serve as *ad hoc* reviewers for the SACC is based on the function of the Committee and the expertise needed to address the Agency's charge to the Committee. No interested scientists shall be ineligible to serve by reason of their membership on any other advisory committee to a federal department or agency or their employment by a federal

department or agency, except EPA. Other factors considered during the selection process include availability of the prospective candidate to fully participate in the Committee's reviews, absence of any conflicts of interest or appearance of loss of impartiality, independence with respect to the matters under review, and lack of bias. Although financial conflicts of interest, the appearance of loss of impartiality, lack of independence, and bias may result in non-selection, the absence of such concerns does not assure that a candidate will be selected to serve on the SACC.

Numerous qualified candidates are often identified for SACC reviews. Therefore, selection decisions involve carefully weighing a number of factors including the candidates' areas of expertise and professional qualifications and achieving an overall balance of different scientific perspectives across reviewers. The Agency will consider all nominations of prospective candidates for service as *ad hoc* reviewers for the SACC that are received on or before the date listed in the **DATES** section of this document. However, final selection of *ad hoc* reviewers is a discretionary function of the Agency. At this time, EPA anticipates selecting approximately 8-12 *ad hoc* reviewers to assist the SACC in their review of the designated topic.

EPA plans to make a list of candidates under consideration as prospective *ad hoc* reviewers for this review available for public comment by mid to late February 2023. The list will be available in the docket at <http://www.regulations.gov> (docket ID number EPA-HQ-OPPT-2022-0918) and on the SACC website. You may also subscribe to the following listserv for alerts regarding this and other SACC-related activities:  
[https://public.govdelivery.com/accounts/USAEPAPPT/subscriber/new?topic\\_id=USAEPAPPT\\_101](https://public.govdelivery.com/accounts/USAEPAPPT/subscriber/new?topic_id=USAEPAPPT_101).

### **III. Virtual Public Meeting of the SACC**

#### *A. What is the purpose of this public meeting?*

The focus of the 4-day virtual public meeting is the SACC peer review of the following two draft documents:

- Draft Proposed Principles of Cumulative Risk Assessment Under the Toxic Substances

Control Act; and

- Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer Requested Phthalate Under the Toxic Substance Control Act.

EPA will be soliciting comments from the SACC on issues related to chemical grouping for purposes of Cumulative Risk Assessment (CRA), health outcomes related to phthalate syndrome, and possible approaches to developing the cumulative hazard and exposure assessment for High-Priority phthalates and a Manufacturer-Requested phthalate. In addition, EPA intends to publish a separate document in the *Federal Register* to announce the availability of and solicit public comment on the two draft documents, at which time EPA will provide instructions for submitting comments and registering to provide oral comments at the meeting. EPA also intends to provide a meeting agenda for each day of the meeting, and, as needed, may provide updated times for each day in the meeting agenda that will be posted in docket and on the SACC website.

*B. Why did EPA develop these documents?*

Between 2020 and 2022 EPA published final scoping documents for twenty High-Priority and three Manufacturer-Requested chemical substances for risk evaluation under TSCA. During the scoping process, EPA received comments from stakeholders urging the Agency to consider evaluating several chemical substances undergoing risk evaluation for cumulative risk to human health. TSCA does not explicitly require EPA to conduct cumulative risk assessments (CRAs). However, TSCA does require EPA to consider the reasonably available information and to use the best available science and to make decisions based on the weight of scientific evidence [15 U.S.C. 2625(h), (i), (k)]. EPA recognizes that for some chemical substances, the best available science may indicate that the development of a CRA is appropriate to ensure that any risks to human health and the environment are adequately characterized.

1. *Proposed principles of CRAs under TSCA.* EPA's document entitled "Draft Proposed Principles of Cumulative Risk Assessment Under the Toxic Substances Control Act" will

describe the fundamental principles of CRA of chemical substances and how they may be applied within the regulatory requirements of TSCA to ensure TSCA risk evaluations are based on the best available science and are protective of human health. This draft document is not intended to be a framework nor a guidance document on conducting CRAs of chemical substances under TSCA, and it will not address cumulative impacts.

*2. Proposed approach for a CRA of phthalates under TSCA.* Recognizing that human exposure to phthalates is widespread and that multiple phthalates can disrupt development of the male reproductive system in laboratory animals at potentially human relevant doses, EPA asked the National Research Council (NRC) of the National Academies of Science to review the health effects of phthalates and determine whether a cumulative risk assessment of phthalates should be conducted, and if so, what approaches could be used for the assessment. In 2008, NRC published their findings to EPA in a final report entitled “Phthalates and Cumulative Risk Assessment: The Task Ahead”

([https://cfpub.epa.gov/si/si\\_public\\_record\\_report.cfm?Lab=NCEA&dirEntryId=202508](https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NCEA&dirEntryId=202508)). In that report, the NRC recommended that a cumulative risk assessment should be conducted for phthalates. EPA’s document entitled “Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer Requested Phthalate Under the Toxic Substance Control Act” will describe EPA’s proposed approach for evaluating a subset of High-Priority and Manufacturer-Requested phthalates for cumulative risk to human health under TSCA based on the principles of CRA described in EPA’s draft principles document referenced previously. EPA’s draft proposed approach will follow many of the recommendations made by the NRC in 2008. This draft document is not a CRA, and no risk estimates are presented. Instead, this draft document will outline several options EPA is considering for conducting a phthalate CRA under TSCA.

*C. How can I access the documents submitted for review to the SACC?*

EPA is planning to release the two draft documents mentioned above and all background



documents, related supporting materials, and draft charge questions provided to the SACC by late February 2023. At that time, EPA will publish a separate document in the *Federal Register* to announce the availability of and solicit public comment on the two draft documents and provide instructions for submitting comments and registering to provide oral comments. These materials will also be available in the docket through <https://www.regulations.gov> (docket ID number EPA-HQ-OPPT-2022-0918) and the SACC website. In addition, as additional background materials become available and are provided to the SACC, EPA will include those additional background documents (e.g., SACC members and consultants participating in this meeting and the meeting agenda) in the docket and on the SACC website.

*D. How can I participate in the virtual public meeting?*

The public virtual meeting will be held via a webcast platform such as “Zoom.gov” and audio teleconference. You must register online to receive the webcast meeting link and audio teleconference information. Please follow the registration instructions that will be announced on the SACC website in February. You may subscribe to the following listserv for alerts regarding this and other SACC-related activities:

[https://public.govdelivery.com/accounts/USAEPAPPT/subscriber/new?topic\\_id=USAEPAPPT\\_101](https://public.govdelivery.com/accounts/USAEPAPPT/subscriber/new?topic_id=USAEPAPPT_101).

**Authority:** 15 U.S.C. 2625(o); 5 U.S.C appendix 2 *et. seq.*

**Dated:** December 16, 2022.

**Michal Freedhoff,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

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